

42173-P004US

*JPW*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In application of: John Keimel, et al.

Serial No.: 10/803,711

Filing Date: March 18, 2004

Art Unit: 1616

Title: Methods and Systems for Treatment of Neurological Diseases of the Central Nervous System

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

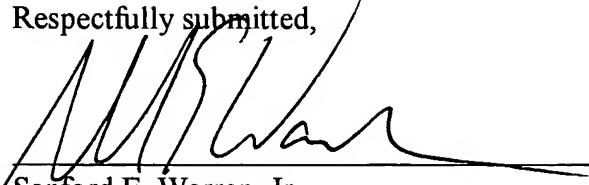
Applicant hereby submits the following references in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of the references cited in the attached PTO/SB/08A are not enclosed nor required; copies of the referenced cited in the attached PTO/SB/08B are enclosed for the examiner's reference. Furthermore, pursuant to 37 C.F.R. § 1.97(g) and (h), no representation is made that this is material to patentability of the present application or that a search has been made.

Applicant hereby submits that claims of Applicant's above-referenced patent application are patentably distinguishable from these references.

It is believed that no fees are due; however, the Director of Patents and Trademarks is hereby authorized to charge any fees relating to this Information Disclosure Statement under 37 CFR § 1.17 to Deposit Account No 23-2426 (referencing docket no. 42173-P004US) of WINSTEAD SECHREST & MINICK P.C.

Date: 7/26/04

Respectfully submitted,


  
Sanford E. Warren, Jr.  
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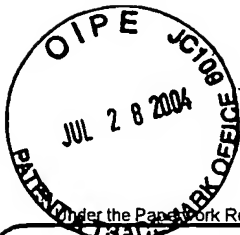
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42173-P004US 7/10/2004



PTO/SB/08A (04-03)

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STATEMENT BY APPLICANT**

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Sheet 2 of 4

**Complete if Known**

Application Number	10/803,711
Filing Date	March 18, 2004
First Named Inventor	Keimel, et al.
Art Unit	1616
Examiner Name	Unknown
Attorney Docket Number	42173-P003US

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 6,594,880	07/22/03	Elsberry	
		US- 6,599,919	07/29/03	Fan, et al.	
		US- 6,613,322	09/02/03	Tabas, et al.	
		US- 6,638,712	10/28/03	Lobel, et al.	
		US- 2002/0052311	05/02/02	Solomon, et al.	
		US- 2002/0110551	08/15/02	Chen	
		US- 2002/0127219	09/12/02	Okkels, et al.	
		US- 2002/0142985	10/03/02	Dwek, et al.	
		US- 2002/0164758	11/07/02	Kakkis	
		US- 2003/0087803	05/08/03	Yatvin, et al.	
		US- 2003/0129186	07/10/03	Beliveau, et al.	
		US- 2003/0133904	07/17/03	Dagan, et al.	
		US- 2003/0161809	08/28/03	Houston, et al.	
		US- 2003/0215432	11/20/03	Matalon	
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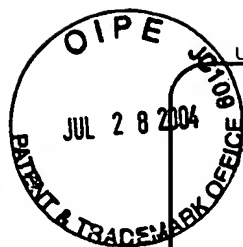
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		WO 98/011245	03/19/98	Gueiros-Filmo, et al.		
		WO 03/055538	07/10/03	Jin		
		EP 0 290 891 B1	11/17/88	Sabel, et al.		
		WO 03/090820 A1	11/06/03	Hanker, et al.		

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Sheet 1 of 4

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		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,222,982	06/29/93	Ommaya	
		US- 5,385,582	01/31/95	Ommaya	
		US- 5,433,946	07/18/95	Allen, Jr., et al.	
		US- 5,716,614	02/10/98	Katz, et al.	
		US- 5,798,366	08/25/98	Platt, et al.	
		US- 5,814,014	09/29/98	Elsberry, et al.	
		US- 5,846,220	12/08/98	Elsberry	
		US- 6,056,725	05/02/00	Elsberry	
		US- 6,093,180	06/25/00	Elsberry	
		US- 6,410,250	06/25/02	Gueiros-Filho, et al.	
		US- 6,458,574	10/01/02	Selden, et al.	
		US- 6,503,242	01/07/03	Elsberry	
		US- 6,551,290	04/22/03	Elsberry, et al.	
		US- 6,537,785	03/25/03	Canfield	
		US- 6,569,661	05/27/03	Qin, et al.	
		US- 6,582,692	06/24/03	Podsakoff, et al.	
		US- 6,583,158	06/24/03	Fan, et al.	
		US- 6,585,971	07/01/03	Kakkis	
		US- 6,589,964	07/08/03	Fan, et al.	

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		WO 02/087510	11/07/02	Lebowitz, et al.		
		WO 02/038171	05/16/02	Kakkis		
		WO 02/007671	01/31/02	Lavi, et al.		
		WO 02/004616	01/17/02	Hendstrand, et al.		
		WO 99/056770	11/11/99	Chang, et al.		

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Sheet	3	of	4
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**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Kmiec, "Gene Therapy," American Scientist, 87(3): 240 (1999)	
		Woo, "The Last Word: Researchers React to Gene Therapy's Pitfalls and Promises," FDA Consumer Magazine, Sept.-Oct. (2000)	
		Young, "'Miracle' gene therapy trial halted," New Scientist, 14:30 (2002)	
		Hsu et al., "Niemann-Pick disease type C (a cellular cholesterol lipidosis) treated by bone marrow transplantation," Bone Marrow Transplantation, 24:103-107 (1999)	
		Yeager et al., "Bone marrow transplantation for infantile ceramidase deficiency (Farber disease)," Bone Marrow Transplantation, 26:357-363 (2000)	
		von Specht et al, "Enzyme replacement in Tay-Sachs disease," Neurology, Jun; 29(6):848-54 (1979)	
		Dobrenis and Rattazzi, "Neuronal lysosomal enzyme replacement using fragment C of tetanus toxin," Proc. Natl. Acad. Sci. U S A, Mar 15; 89(6):2297-301 (1992)	
		Kakkis, "Normalization of Carbohydrate Storage in Brain Tissue Using an MPS I Model," Ninth International Congress on Inborn Errors of Metabolism, September 3, 2003, Brisbane, Australia	
		Levy, R. Implanted Drug Delivery Systems for Control of Chronic Pain. Chapter 19 of Neurosurgical Management of Pain. New York, NY: Springer-Verlag; 1997	
		Athappilly et al., "Crystallographic analysis of the pH-dependent binding of iminobiotin by streptavidin," Protein Science, 6(6):1338-42 (1997)	

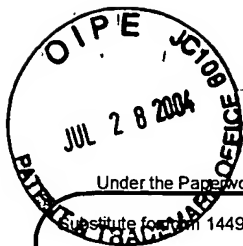
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		Chilkoti et al., "Site-directed mutagenesis studies of the high-affinity streptavidin-biotin complex: Contributions of tryptophan residues 79, 108, and 120," Proc. Natl. Acad. Sci. USA, 92: 1754-1758 (1995)	
		Chian et al., "Insulin-like growth factor-1: tetanus toxin fragment C fusion protein for improved delivery of IGF-1 to the CNS," Program No. 413.14, Abstract Viewer, Society for Neuroscience Annual Meeting (2003)	
		C. Matthews et al., "A streptavidin-tetanus toxin C fragment fusion protein for the delivery of biotinylated molecules to neurons," Program No. 733.18 Abstract Viewer, Society for Neuroscience Annual Meeting (2003)	
		Larson et al., "Glial-derived neurotrophic factor:tetanus toxin fragment C fusion protein for targeted delivery of GDNF to neurons," Program No. 299.5, Abstract Viewer, Society for Neuroscience Annual Meeting (2003)	
		Zirzow et al., "Delivery, distribution, and neuronal uptake of exogenous mannose-terminal glucocerebrosidase in the intact rat brain," Neurochem Res., 24(2):301-305 (1999)	

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